10/10/03

TITLE 105: DEPARTMENT OF PUBLIC HEALTH

CHAPTER 141.000: LICENSURE OF HOSPICE PROGRAMS

105 CMR 141.001 (2003)

Preamble

Pursuant to Chapter 283 of the Acts of 2002, which amended the hospice program licensure statute at M.G.L. Chapter 111, section 57D, the Department is authorized to establish regulations for the licensure of not more than 6 hospice inpatient facilities directly owned and operated by licensed hospice programs. Only hospice programs licensed for two years prior to the effective date of these amendments shall be eligible to apply for licensure of a hospice inpatient facility as an added component of their license. The licensing, administrative, programmatic, clinical and physical plant requirements each hospice inpatient facility must meet are described in these regulations. The Department will accept applications for hospice inpatient facilities beginning 90 days from the effective date of these amendments and until 6 applications are approved.

The Department by statute is required to conduct an interim review of the number of approved hospice inpatient programs after November 12, 2004 and a final review after November 12, 2006 to determine whether the number of programs should be increased or decreased.

141.001: Purpose

105 CMR 141.000 sets forth standards for the conduct and licensing of hospice programs.

141.002: Authority

105 CMR 141.000 is adopted under authority of M.G.L. c. 111, § § 3 and 57D.

141.003: Citation

105 CMR 141.000 shall be known and may be cited as 105 CMR 141.000: Licensure of Hospice Programs.

141.010: Scope

105 CMR 141.000 applies to every hospice subject to licensure under M.G.L. c. 111, § 57D.

141.020: Definitions

The following terms as used in 105 CMR 141.000 shall be interpreted as follows, unless the context or subject matter clearly requires a different interpretation:

Commissioner means the Commissioner of Public Health or his/her designee.

Department means the Massachusetts Department of Public Health.

Direct service volunteer shall mean a lay or professional person who offers his/her services to a hospice without compensation and whose primary volunteer activities are contact with and support of hospice patients/families.

Reimbursement for a volunteer's expenses in providing services shall not be considered compensation. A direct service volunteer is considered one of the hospice's personnel.

Governing body shall mean any of the following:

(1) The board of directors or trustees of a hospice which is a not-for-profit corporation;

(2) The board of directors or trustees of a hospice which is a for-profit corporation;

(3) The proprietor or owners of a hospice which is a solely owned business or partnership; or

(4) The policy making body of a hospice which is operated by a government agency, or the policy making body or agency head of the government agency.

Hospice or hospice program means palliative and supportive care and other services provided by an interdisciplinary team under the direction of an identifiable hospice administration to terminally ill patients with a limited life expectancy and their families. Services shall be provided to meet the physical, emotional, and spiritual needs experienced during the course of their illness, death, and bereavement at home, in the community, and in facilities. Such services shall include, but not be limited to, physician's services, nursing care provided by or under the supervision of a registered nurse, social services, volunteer services, and counseling services provided by professional or volunteer staff under professional supervision. Hospice is a centrally coordinated program that ensures continuity and consistency of home and inpatient care provided directly through an inpatient facility operating under its hospice license or through an agreement.

For the purposes of 105 CMR 141.000, a hospice program shall not include a hospice program operated by the Commonwealth or the United States government.

Hospice inpatient facility means a palliative care facility that cares solely for hospice patients requiring short-term, general inpatient or respite care and is owned and operated directly by a hospice program under the license issued to that program pursuant to M.G.L. c.111 § 57D.

Inpatient care or services means short-term, general inpatient care provided either through a contract arrangement in a hospital or long term care facility or directly by a hospice program in its hospice inpatient facility to provide pain control and symptom management that cannot be accomplished in the home or community.

Licensee means any person holding a license to operate a hospice. In the case of a licensee which is

not a natural person, the term "licensee" shall also mean any shareholder owning 5% or more of any class of the outstanding stock; any limited partner owning 5% or more of the partnership interests and any general partner of a partnership licensee; any trustee of any trust licensee; any sole proprietor of any licensee which is a sole proprietorship; any mortgagee in possession; and any executor or administrator of any licensee which is an estate.

Palliative care means the care of patients diagnosed with progressive disease for whom the focus is the relief of suffering. Palliative care promotes optimal relief of pain and other physical symptoms and enhances the patient and family's quality of life through support for emotional, social and spiritual priorities. A hospice inpatient facility shall not directly provide care such as surgery that is commonly considered acute care appropriately provided solely by a hospital licensed to provide medical/surgical services.

Patient is an individual in the terminal stage of illness who, alone or in conjunction with a family member or members, has voluntarily requested admission and been accepted into a hospice.

Patient/family is the unit identified as the recipient of hospice care which consists of the patient and those individuals who are closely linked with the patient including the immediate family, the primary care giver and individuals with significant personal ties.

Pediatric patient means a person under age 19.

Physician means an individual registered by the Board of Registration in Medicine under M.G.L. c.112, § 2 as a qualified physician.

Primary care giver means a person designated by the patient who is responsible for the patient's care and support in the home on a 24-hour basis.

Registered Nurse means an individual registered under M.G.L. c. 112, § 74.

Respite care means hospice services provided in a patient's home, hospital, long term care facility or hospice inpatient facility to relieve temporarily the patient's family or other caregivers from unforeseen emergencies or the daily demands of caring for the patient.

Social Worker means an individual who is currently licensed to practice social work in Massachusetts pursuant to M.G.L. c. 112, § 131 under the licensure categories of Licensed Independent Practitioner of Clinical Social Work, or Licensed Certified Social Worker or Licensed Social Worker.

141.025: Special Projects

The Department will consider proposals for special projects for the innovative delivery of hospice services. No such proposal shall be implemented without prior written approval of the Department. Such plans shall be implemented only on an experimental basis and subject to renewal of the approval by the Department at such periods as the Department shall fix.

141.099: Compliance with Requirements

(A) Unless otherwise provided, all hospice programs licensed pursuant to this chapter shall meet the requirements set forth in 105 CMR 141.000. Programs operated by a hospital licensed pursuant to M.G.L. c. 111, § 51 shall meet the requirements of 105 CMR 141.100 and 141.200 through 141.212.

(B) The Commissioner may waive the applicability to a particular hospice program of one or more of the requirements imposed on hospice programs by 105 CMR 141.000 if:

(1) the Commissioner finds that:

(a) compliance would cause undue hardship to the hospice program;

(b) the hospice program is in substantial compliance with the requirement; and

(c) the hospice program's non-compliance does not jeopardize the health or safety of its patients and does not limit the hospice program's capacity to give adequate care; and

(2) the hospice program provides to the Commissioner written documentation supporting its request for a waiver.

141.100: Requirement of License

(A) A hospital licensed pursuant to M.G.L. c. 111, § 51 which intends to operate a hospice program shall obtain approval from the Department indicating that it meets the requirements in 105 CMR 141.099(A) for operating such a program. Upon a determination that the hospital meets the relevant requirements, the Department shall cause the license issued to a hospital pursuant to 105 CMR 130.120 to indicate that the licensee is authorized to operate a hospice program as a specific service of the hospital.

(B) All other hospice programs shall obtain a license pursuant to M.G.L. c. 111, § 3 and 57D and 105 CMR 141.000, said license to be obtained prior to operating such a program except as otherwise provided in 105 CMR 141.103.

(C) A hospice program shall not operate in the Commonwealth or use the word ‘hospice’ or ‘hospice program’ without a hospice license issued by the Commissioner. A person not licensed to provide hospice services shall not use the word ‘hospice’ in a title or description of a facility, organization, program, service provider or services or use any words, letters, abbreviations or insignia indicating or implying that the person holds a license to provide hospice services.

141.101: Application for a License

(A) Application for original or renewal licensure shall be made on forms prescribed by and available from the Department. Every application shall be notarized and signed under the pains and penalties of perjury by the applicant or a person authorized to act on behalf of the applicant.

(B) In support of an application for an original or renewal license, each applicant shall submit the following information, updated as required by 105 CMR 141.106.

(1) Information concerning ownership and control that identifies:

(a) If owned by an individual, partnership or trust, the names and ownership percentages of such individual, partners or trustees, except that, in the case of a limited partnership, such information shall be provided only for those limited partners owning 5% or more of the partnership interest and the general partner.

(b) If owned by a for profit corporation, the names of all stockholders who hold five percent or more of any class of the outstanding stock, specifying the percentage owned.

(c) If owned by a not for profit corporation, the names of the members and directors of the corporation.

(d) The name and ownership percentage of each individual who directly or indirectly has any ownership interest of 5% or more, unless otherwise provided pursuant to 105 CMR 141.101(B)(1)(a), (b) or (c).

(2) A copy of its by-laws and articles of incorporation, partnership agreement, trust instrument, or other charter, and if ownership of the hospice program has been transferred, satisfactory documentary evidence (such as a contract or a deed) showing that ownership of the hospice has been transferred to the applicant, which demonstrates legal capacity to provide the services for which the license is sought.

(3) Only hospice programs licensed for two years prior to the effective date of these amendments shall be eligible to apply for licensure of a hospice inpatient facility as an added component of their license.

(4) Any information required by the Commissioner as part of the application, including such additional information concerning ownership and control as the Commissioner may require.

141.102: Other Licensing Requirements

(A) Ownership Interest. An applicant or licensee must be the owner of the premises on which the hospice program administration and any hospice inpatient facility directly operated by the hospice program is operated or lessee of the premises for at least one year.

(B) Name. Each hospice program applying for a license shall be designated by permanent and distinctive name that shall appear on the application for a license. To avoid public confusion or misrepresentation, this name shall not be changed without prior approval by the Department.

(C) Fees. The hospice license fee shall accompany every application and shall be as set by the Department or the Executive Office of Administration and Finance. Payment of the fee shall be by check or money order payable to the Commonwealth of Massachusetts.

(D) Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. If a hospice program intends to perform on its patients any laboratory tests, such as glucose monitoring or fecal occult blood tests, the hospice program must apply for and receive, through the Department's Clinical Laboratory Program, a CLIA Certificate of Waiver prior to performing these tests.

(E) Any hospice that is authorized to provide inpatient care directly in a hospice inpatient facility shall, prior to the operation of such facility, and, as a prerequisite for subsequent licensure renewal, submit to the Department the following:

(1) a certificate of inspection of the egresses, the means of preventing the spread of fire, and the apparatus for extinguishing fire, issued by the Department.

(2) a certificate of inspection, issued by the head of the local fire department, certifying compliance with local ordinances.

(3) evidence that the licensee owns the premises on which the facility is operated or has a valid lease agreement.

(F) Any hospice that is authorized to provide inpatient care directly in a hospice inpatient facility, must submit and receive the Department's approval of architectural plans and specifications for the hospice inpatient facility prior to the construction of such facility.

In the case of alterations or additions to an existing hospice inpatient facility, or conversion of an existing building, preliminary and final architectural plans and specifications shall be submitted to the Department for approval prior to said alterations or additions or conversion.

(G) Any hospice that is authorized to provide inpatient care directly in a hospice inpatient facility must demonstrate to the satisfaction of the Commissioner that it meets the requirements set forth in 105 CMR 141.204(H)(4).

141.103: Timing of Application

(A) In the case of a transfer of ownership, the application shall be submitted no later than 48 hours following the transfer. See 105 CMR 141.104.

(B) In the case of a renewal license, the application shall be submitted at least three months prior to expiration of the license.

(C) An application filed in accordance with the provisions of 105 CMR 141.103(A) or (B) shall have the effect of a license until the application is acted upon by the Department.

(D) The Department will accept applications for hospice inpatient facilities beginning 90 days from the effective date of these amendments and until 6 applications are approved.

141.104: Transfer of Ownership

(A) The proposed licensee shall submit a Notice of Intent to acquire a hospice program to the Department at least 30 calendar days in advance of any transfer of ownership. Transfer of ownership shall be deemed to have occurred where there has been:

(1) A transfer of majority interest in the ownership of a program;

(2) In the case of a for profit corporation, transfer of a majority of any class of the stock thereof:

(3) In the case of a non-profit corporation, such changes in the corporate membership and/or trustees as the Department determines to constitute a shift in control of the program;

(4) In the case of a partnership, transfer of a majority of the partnership interest;

(5) In the case of a trust, change of the trustee or a majority of trustees.

A transfer of ownership shall be deemed to have occurred where foreclosure proceedings have been instituted by a mortgagee in possession.

(B) Any person applying for a license as a result of any transfer of ownership shall file an application for licensure within 48 hours of the transfer or such longer period as the Commissioner shall prescribe. If the Notice of Intent was not timely filed, at the discretion of the Commissioner, an application received as a result of a transfer of ownership will not be considered as filed for 30 calendar days, or such longer period as the Commissioner shall designate, after such application is received.

(C) An application filed as a result of a transfer of ownership, if timely filed, shall have the effect of a license until such time as the Department takes action on the application. If not timely filed, such application shall not have such effect.

(D) Any notice of hearing, order or decision which the Department or the Commissioner issues for a hospice program prior to a transfer of ownership shall be effective against the former owner prior to such transfer and, where appropriate, the new owner, following such transfer unless said notice, order or decision is modified or dismissed by the Department or by the Commissioner.

(E) A transfer of ownership shall not be recognized and the new owner shall not be considered suitable for licensure when the transfer is proposed or made to circumvent the effect and purpose of 105 CMR 141.000. The Department shall consider the following factors in determining whether a transfer has been proposed or made to circumvent 105 CMR 141.000:

(1) The transferor's record of compliance with Department licensure laws and regulations;

(2) The transferor's current licensure status;

(3) The transferor's familial, business and/or financial relation to the transferee;

(4) The terms of the transfer;

(5) The consequences of the transfer.

141.105: Acceptance of Application

(A) The Department shall not accept an application for an original or renewal license unless:

(1) The application includes all information required by the Commissioner;

(2) The application and all required attachments and statements submitted by the applicant meet the requirements of 105 CMR 141.000;

(3) The applicant has paid all required fees.

(B) In the case of the transfer of ownership for a hospice program, the application of the new owner for a license shall not have the effect of a license until such time as the Department takes action on the application when the application is not filed in accordance with 105 CMR 141.105(A).

141.106: Updating of Ownership Information

Ownership and control information submitted under the requirements of 105 CMR 141.000 or otherwise required by the Commissioner shall be kept current by each licensee. Any document which amends, supplements, updates or otherwise alters any ownership and control document required to be filed with the Department shall be submitted to the Department within 30 days of the execution thereof. Any changes in, or additions to, the content of the information contained in any

document required to be filed shall be reported to the Department within 30 days of such change or addition.

141.107: Evaluation of Application

The Department shall not approve an application for original or renewal license unless:

(1) The Commissioner has conducted an inspection or other investigation of the facility and has determined that the applicant complies with 105 CMR 141.000;

(2) The Commissioner has conducted an investigation of the applicant(s) and determined the applicant(s) are responsible and suitable to establish or maintain a hospice program.

141.108: Evidence of Responsibility and Suitability

(A) In determining whether an applicant is responsible and suitable to be granted a hospice license, the Department shall consider all relevant information including, but not limited to, the following:

(1) the proposed licensee's history of prior compliance with Massachusetts state laws governing health facility or services operation, and 105 CMR. Assessment of this factor shall include the ability and willingness of the applicant to take corrective action when notified by the Department of any regulatory violations;

(2) the proposed licensee's financial capacity to provide services in compliance with state law and 105 CMR 141.000 as evidenced by sufficiency of present resources and assessment of past history, including financial involvement with health care facilities that have filed petitions for bankruptcy;

(3) the history of criminal conduct of the applicant, and of the hospice administrator, officers and directors as evidenced by criminal proceedings against those individuals which resulted in convictions, or guilty pleas, or pleas of nolo contendere, or admission of sufficient facts; and

(4) the proposed licensee's history of statutory and regulatory compliance for health care facilities in other jurisdictions, including proceedings in which the applicant was involved which proposed or led to a limitation upon or a suspension, revocation, or refusal to grant or renew a health care facility license or service's license or certification for Medicaid or Medicare to the proposed licensee.

(B) The Commissioner will consider the evidence produced and make licensure recommendations accordingly.

141.109: Right to Visit and Inspect

The Department or its agents may visit and inspect a program subject to licensure under M.G.L. c. 111, § 57D at any time without prior notice in order to determine the program's compliance with state law and 105 CMR 141.000. All parts of the program, all staff and activities, and all records are subject to such visit and inspection.

141.110: Frequency of Inspection

An inspection or other investigation shall be made prior to the issuance of every license. Additional inspections may be made, consistent with the availability of staff, whenever the Commissioner deems it necessary for the enforcement of 105 CMR 141.000.

141.111: Deficiency Statements

After every inspection in which any violation of 105 CMR 141.000 is observed, the Commissioner shall prepare a deficiency statement citing every violation observed, a copy of which shall be sent to the program.

141.112: Plan of Correction

(A) A hospice shall submit to the Commissioner a written plan of correction of violations cited in a deficiency statement prepared pursuant to 105 CMR 141.111 within ten days after the deficiency statement is sent.

(B) Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with 105 CMR 141.000 will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.

(C) The Commissioner shall review the plan of correction for compliance with the requirements of 105 CMR 141.000 and will notify the hospice of either the acceptance or rejection of the plan. An unacceptable plan must be amended and resubmitted within five days of the date of notice.

141.120: Issuance of License

Upon the approval of the application for a license the Department shall issue a license to the applicant. The license shall not be transferable. The licensee shall be responsible to ensure compliance with all applicable rules and regulations.

The license shall contain the name and address of the hospice, and, in the case of a hospice authorized to directly own and operate a hospice inpatient facility pursuant to the provisions of 105 CMR 141.102 and 141.204(H), the name and address of any such facility.

141.121: Period of License

(A) The term of the license shall be, unless otherwise provided in 105 CMR 141.121, for two years from the date of issuance, and any renewals thereof shall also be for two years.

(B) The Department may issue a provisional license for a period of no more than one year to a hospice program which is not in full compliance with applicable requirements but which the Department finds is in substantial compliance with such requirements and demonstrates potential for achieving full compliance within the provisional licensure period. Consecutive provisional licenses shall not be issued to a hospice.

(C) Provided a licensed hospice submits a timely application for a renewal license, its previous license shall be valid until the Department acts on its renewal application. Upon receipt of a renewal license, the hospice shall return the expired license to the Department by certified mail.

(D) An application filed as a result of a transfer of ownership, if timely filed, shall have the effect of a license until such time as the Department takes action on the application. If not timely filed, such an application shall not have such effect.

141.122: Posting of License

The current license from the Department shall be posted in a conspicuous place on the program office premises and, in the case of a hospice that directly owns and operates a hospice inpatient facility, a copy of the license, which has been clearly marked as a copy, shall be posted in a conspicuous place on the hospice inpatient facility premises.

141.123: Renewal of License

(A) The Department shall send each licensee notification of the need to renew its license and the necessary application forms no later than 90 days prior to the expiration of an existing license.

(B) The licensee shall complete and return the application form within 30 days of its receipt of notification from the Department, together with such other information and materials as the Department shall deem appropriate.

141.130: Suspension of a License

(A) The Commissioner may, upon finding that continued operation of a hospice poses an imminent risk to the health or safety of the patients, suspend the license of the hospice without a prior hearing.

(B) Upon suspension, the Commissioner shall give to the program a written notice setting forth the reasons for the suspension. The suspension shall take effect immediately upon issuance of the notice.

(C) Within 14 days after receipt of notice that a license has been suspended, the licensee may appeal such suspension by filing a Notice of Claim for an Adjudicatory Proceeding pursuant to 801 CMR 1.00 et seq. After receipt of a Notice of Claim for Adjudicatory Proceeding, the Commissioner shall schedule an adjudicatory hearing for a date as early as is practicable.

(D) In cases of suspension of a license, the hearing officer shall determine whether the Commissioner has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the suspension, an imminent risk to the health or safety of the hospice's patients.

(E) The decision of a hearing officer in any adjudicatory proceeding conducted under 105 CMR 141.130 shall be reviewed by the Commissioner and the Public Health Council and their decision upon this review shall constitute final agency action.

141.131: Denial, Revocation, and Refusal to Renew Licenses

(A) A license may be denied, revoked, or refused renewal for cause. Cause shall include but not be limited to the following (each of which shall constitute cause in and of itself):

(1) Lack of legal capacity to provide the service(s) to be covered by a license as determined pursuant to 105 CMR 141.101 and 141.102;

(2) Lack of responsibility and suitability to operate a hospice, as determined pursuant to 105 CMR 141.108.

(3) Failure to submit the required license fee.

(4) Violation of any state statute pertaining to hospice licensure.

(5) Failure to give proper patient care to hospice patients.

(6) Violation of any applicable provision of 105 CMR 141.000 and:

(a) Failure to submit an acceptable plan of correction pursuant to 105 CMR 141.112 or;

(b) Failure to remedy or correct a cited violation by the date specified in the plan of correction as accepted or modified by the Department.

(7) Denial of entry to agents of the Department.

(8) Refusal to permit inspection or photocopying by the Department of any records or other information as necessary to determine compliance with 141.000 *et seq*.

(9) There is a reasonable basis for the Department to conclude that there is a discrepancy between representations by a program as to the services to be afforded clients and the services actually rendered or to be rendered.

(B) Whenever the Commissioner denies an application for initial licensure or determines that a license should be revoked or refused renewal, the Commissioner shall provide written notice thereof to the applicant or licensee.

(C) Within 21 days after receipt of notice that an application for initial licensure has been denied or a determination that a licensee should be revoked or refused renewal, the applicant or licensee may appeal such action by filing a Notice of Claim for an Adjudicatory Proceeding pursuant to 801 CMR 1.00 et seq.

(D) The hearing officer shall determine whether the Commissioner has proved by a preponderance of the evidence that the license should be denied, revoked or refused renewal based on relevant facts as they existed at or prior to the time the Commissioner provided written notice of his action.

(E) The decision of a hearing officer in any adjudicatory proceeding conducted under this section shall be reviewed by the Commissioner and the Public Health Council and their decision upon this review shall constitute final agency action.

141.140: Closing of a Program

(A) Approval. If a program intends to cease operation for a period greater than seven consecutive days, written approval for a specified period shall be obtained from the Commissioner. If circumstances are such that it is not possible to obtain approval from the Commissioner prior to closing, such approval shall be obtained within 72 hours of closing. Failure to obtain approval and closure of the program for more than seven days shall constitute abandonment of license.

(B) Patient Transfer. When a hospice ceases to operate through license denial, refusal to renew, suspension, revocation or closure pursuant to 105 CMR 141.140(A), the licensee will be responsible for the transfer of patients to a suitable program.

(1) At least 21 days prior to ceasing operation, staff at the hospice program will orally or in writing notify each patient/family that the program will cease operation. Staff will also notify each patient/family of the referral plan to another appropriate program for continuation of services.

(2) Staff at the hospice to be closed will be responsible for developing a written referral plan to be placed in the patient record for each ongoing case. Staff will also refer the patient to a program which will be responsible for continuing service.

(3) Clinical records shall be transferred to the receiving agency provided that a signed authorization to release such records shall be obtained from each patient/family prior to the transfer.

141.141: Temporary Interruption of Service

If a hospice finds that any of the services required under 141.000 cannot be provided to patients for a temporary period of time, the hospice shall report such a temporary interruption of service to the Department as soon as the interruption of service is known to the hospice.

141.200: Governing Body

(A) The hospice shall have a governing body that assures full legal authority and responsibility for determining, implementing and monitoring policies governing the hospice's total operation.

(B) The governing body shall designate an administrator who shall be responsible on a day-to-day basis for the management and operation of the hospice program.

(C) The governing body shall be responsible for:

(1) managing the fiscal affairs and operation of the hospice program;

(2) assuring quality care and services;

(3) ensuring compliance of the hospice with all applicable federal, state and local laws, rules and regulations;

(4) providing for coordinated, interdisciplinary hospice services available 24 hours a day, seven days a week;

(5) ensuring adequate staff and resources to provide continuity of care based on the needs of the persons served;

(6) adopting, amending and implementing by-laws;

(7) adopting the hospice budgets and controlling assets and funds;

(8) establishing committees as appropriate.

141.201: Administration

(A) Administrator.

(1) Each hospice shall designate a hospice administrator who is responsible to the governing body, either directly or through the governing body's chief executive officer, for the administration and management of the hospice.

(2) The hospice administrator shall be a person who has a minimum of two years of relevant experience in the health care, human services or related fields, which shall include at least one year of supervisory/administrative experience.

(3) The duties of the administrator shall include but not be limited to:

(a) Directing the hospice and ensuring implementation of policies and procedures regarding all activities and services provided in the hospice, whether provided through staff employed directly by the hospice, by volunteers or through contract arrangement;

(b) Designating, in writing, an alternate to act in his or her absence;

(c) Implementing administrative and personnel policies;

(d) Implementing an effective budgetary and accounting system;

(e) Implementing a quality assurance mechanism to assess the overall hospice program;

(f) Keeping the governing body informed of the hospice's operations;

(g) Appointing qualified hospice staff members when and where appropriate and ensuring adequate staff education and evaluations;

(h) Developing and proposing an annual budget for adoption by the governing body and managing the financial aspects of the hospice;

(i) Ensuring that action is taken to correct problems identified either through patient/family record reviews, fiscal audits, or as a result of patient/family recommendations;

(j) Ensuring a public education program through contact with community organization to inform consumers about hospice care; and

(k) Ensuring that patient care services are appropriately coordinated.

(l) Ensuring incident reports are submitted to the Department as required under these regulations.

(B) Clinical Services Coordinator.

(1) An individual shall be designated to be responsible for coordinating the clinical services provided by the individuals providing care to hospice patients. Clinical services include at least nursing, medical, social work and counseling.

(2) The individual responsible for clinical services coordination shall be a health care professional possessing academic training and experience in direct patient care and shall be qualified to coordinate the clinical services provided by the hospice.

(3) A staff person serving in another position within the hospice may also be the coordinator of clinical services if he/she meets the requirements for both positions and can adequately carry out the duties of both positions.

(C) Personnel Policies.

Each hospice shall establish and maintain current written personnel policies and personnel practices and procedures that encourage good patient/family care. These policies and procedures shall be reviewed and updated annually and shall cover at least the following:

(1) Position descriptions for each category of employee, volunteer, or contracted personnel which clearly identify qualifications, duties, responsibilities and accountability of the individual assuming the position. Work assignments shall be consistent with job descriptions, qualifications and education.

(2) Orientation to hospice care for all personnel, including employees of contracting agencies and volunteers.

(3) Organized staff support programs to help staff cope with their job responsibilities.

(4) Employee health policies that include, as a minimum, adequate provisions for preventing the transmission of communicable diseases.

(5) Regular evaluation of staff performance.

(D) Administrative Records.

(1) Each hospice shall maintain current, complete and accurate administrative records. The hospice shall make all administrative records available promptly to any agent of the Department seeking to determine compliance with 105 CMR 141.000.

(2) Administrative records shall include:

(a) updated articles of organization and by-laws;

(b) minutes of the meetings of the governing body;

(c) an organizational chart;

(d) personnel records for each employee including evidence of any required license or registration number, documentation of any specialty certification, education and job experience.

(E) Incident Reporting.

(1) All incidents seriously affecting the health or safety of patients resulting from acts or omissions of hospice program employees, including those working for the hospice through a contract arrangement with another organization, and volunteers shall be recorded and reported accurately to the Department within seven days of the occurrence. Such reports shall be made in a format prescribed by the Department.
(2) A hospice inpatient facility shall also report immediately any of the following which occurs

on premises covered by its license:
(a) fire,
(b) serious criminal acts, or
(c) pending or actual strike action by its employees, and contingency plans for operation of the hospice inpatient facility.

(3) A hospice program shall make available to the Department all information that may be relevant to the Department's investigation of any incident or complaint, regardless of how reported to the Department.

(4) A hospice program shall make all reasonable efforts to facilitate the Department's attempts to interview any and all potential witnesses who may have information relevant to the Department's investigation of any incident or complaint, regardless of how reported to the Department.

(F) Patient Abuse, Mistreatment, Neglect or Misappropriation of Property.
In accordance with 105 CMR 155.000 Patient and Resident Abuse Prevention, Reporting, Investigation, Penalties and Registry, hospice workers must report suspected abuse, mistreatment, neglect or misappropriation of hospice patient property.

(G) Grievance Procedure.

(1) The hospice patient has the right to voice grievances without discrimination or reprisal. Such grievances include those with respect to treatment that has been furnished as well as that which has not been furnished.

(2) The hospice program must promptly acknowledge and actively work to resolve all oral and written patient grievances.

141.202: Plan of Care/Assessments

(A) A comprehensive plan of care shall be developed by an interdisciplinary hospice care team and if applicable, the patient's attending physician, prior to provision of services. The initial plan of care shall be developed within three days of admission by at least three members of the interdisciplinary team as defined by 105 CMR 141.203, including a registered nurse and the medical director. The initial plan of care shall be reviewed and ratified by the full interdisciplinary team at their next scheduled meeting.

(B) The patient/family shall be permitted and encouraged to actively participate in the care planning process and the provision of care. Such participation shall be documented in the patient/family record.

(C) The plan of care shall include but not be limited to:

(1) pertinent diagnosis and prognosis;

(2) identification of the physical, psychological, social, economic and spiritual status of the patient/family;

(3) need for inpatient care (respite or general), nutritional needs, medication needs, need for management of discomfort and symptom control, and need for management of grief;

(4) plan to address identified needs including scope of services required;

(5) identification of anticipated frequency of services needed;

(6) designation of the primary care giver or alternate plan to provide 24 hour care and support in the patient's home;

(7) identification of the person responsible for coordinating care;

(8) plans instructing the patient/family or designated caregiver in patient care;

(9) plans for support and care at the time of death

(10) plans for providing bereavement care to family

(D) The comprehensive plan of care shall reflect the changing care needs of the patient/family, and be reviewed and revised as necessary but at least twice a month by the interdisciplinary care team. These reviews shall be documented in the patient/family record.

141.203: Interdisciplinary Team

(A) The hospice shall establish an interdisciplinary care team(s) that includes but is not limited to:

(1) medical director

(2) registered nurse

(3) coordinator of volunteers

(4) social worker

(5) spiritual or other counselor

(6) bereavement coordinator

A team member may serve more than one role on the team.

(B) The interdisciplinary team's responsibilities shall include but not be limited to:

(1) establishing a plan of care for each patient/family

(2) conducting regularly scheduled meetings to review the plan of care as needed but at least twice monthly for each patient/family receiving hospice services

(3) encouraging active involvement of the patient/family in development and implementation of plan of care

(4) providing or supervising the provision of hospice care and services

(5) implementing written policies governing the day-to-day provision and evaluation of hospice care and services

(6) monitoring continuity of care across all settings

(C) One member of the interdisciplinary team shall be designated as coordinator of a patient's care and shall be responsible for coordinating the implementation of the plan of care for that particular patient and assuring that all services required for the particular patient's care are in place.

141.204: Required Patient Care Services

(A) A hospice shall provide directly or arrange, pursuant to a written agreement, for the provision of each of the following services at home, in the community and in facilities: physician services, nursing services, social services, direct service volunteer services, counseling services, and inpatient care for palliative reasons.

(B) As needed, the hospice shall provide or arrange for the following services:

(1) personal care homemaker

(2) home health aide

(3) therapeutic (dietary, occupational therapy, physical therapy, speech, hearing, respiratory therapy)

(4) medical supplies and appliances

(5) pharmaceutical

(6) respite services

(C) Physician Services.

(1) Each hospice shall designate a physician to serve as Medical Director. The Medical Director shall have overall responsibility for the medical component of patient care and for ensuring achievement and maintenance of quality standards of professional medical care.

(2) The duties of the medical director shall include but need not be limited to:

(a) Designating another physician to serve as Medical Director in his/her absence.

(b) Consulting and cooperating with the physician or team maintaining the primary responsibility for the patient care pursuant to 105 CMR 141.204(C)(3).

(c) Reviewing clinical material of referring physician to document: basic disease process; the drug regimen; and assessment of patient's health and prognosis at time of admission.

(d) Performing an admission history and physical for each patient who has no other physician.

(e) Maintaining liaison with the patient's attending physician, physician-physician assistant team or physician-nurse practitioner team and encouraging patient's attending physician to provide primary care to his/her patient in collaboration with the interdisciplinary team.

(f) Assisting in developing the plan of care for each patient/family with the coordination of the patient's physician, physician-physician assistant team or physician-nurse practitioner team.

(g) Attending and actively participating in interdisciplinary team meetings.

(h) Reviewing the medical care provided in patients' homes, and in inpatient and outpatient health care facilities.

(i) Maintaining 24 hour, seven days a week medical coverage when attending physicians or physicians designated to act in the attending physician's absence are unavailable.

(j) Acting as a consultant to patient's physician and members of the interdisciplinary team; helping to develop and review patient/family care policies and procedures; serving on the

interdisciplinary care team; and reporting to the administrator regarding medical care delivered to the hospice patient.

(k) Participating in establishing written programmatic guidelines for symptom control (e.g., pain, nausea, vomiting, or other symptoms.)

(3) A hospice must ensure that each patient has a physician, or a team, composed of a physician and either a physician assistant or a nurse practitioner, who maintains the primary responsibility for the patient's medical care. This physician may be the patient's attending physician or may be a physician, including the medical director, selected by the hospice.

(4) Each patient's medical record shall clearly indicate the name of the physician or the members of the physician-physician assistant team or physician-nurse practitioner team who maintain the primary responsibility for the patient's medical care.

(D) Nursing Services.

(1) The hospice shall provide nursing services under the direction and supervision of a designated registered nurse qualified by education and experience to direct hospice nursing care.

(2) Nursing services, including the services of a registered nurse, shall be available seven days a week, 24 hours a day.

(3) The designated registered nurse responsible for supervising nursing services shall work in cooperation with the Administrator and with the individual responsible for clinical services coordination in order to:

(a) develop and implement nursing objectives, policies and procedures;

(b) develop job descriptions for all nursing personnel;

(c) establish staffing and on-call schedules to meet patient/family needs;

(d) develop and implement orientation programs.

(4) A registered nurse shall assess, identify, plan, and evaluate care for the patient/family based on nursing needs.

(a) For hospice programs admitting pediatric patients, a registered nurse with clinical pediatric training and experience shall coordinate the implementation of the plan of care for each pediatric patient.

(5) Nursing care shall be provided in accordance with recognized standards of nursing practice.

(6) All nursing services shall be documented in the patient/family record.

(E) Social Work Services.

(1) The hospice shall provide social work services to the patient and family.

(2) Social work services shall be directed by and shall be provided under the supervision of a licensed certified social worker with an MSW or a licensed independent clinical social worker.

(3) Social work services shall be provided by a licensed social worker qualified by education and experience. Social Worker means an individual who is currently licensed to practice social work in Massachusetts pursuant to M.G.L. c. 112, § 131 under the licensure categories of Licensed Independent Practitioner of Clinical Social Work, or Licensed Certified Social Worker or Licensed

Social Worker.

(4) If social work services are provided solely by one individual, that individual shall be a licensed certified social worker with a MSW or a licensed independent clinical social worker.

(5) The individual responsible for directing and supervising hospice social work services shall work in cooperation with the Administrator and the individual responsible for clinical services coordination in order to:

(a) develop and implement social work objectives, policies and procedures;

(b) develop job descriptions for all social work personnel;

(c) develop staffing and on-call schedules to meet patient/family needs;

(d) develop and implement orientation programs.

(6) A social worker shall assess the patient/family and identify psychosocial needs.

(7) Social work services shall be available seven days a week, as needed.

(8) Social work services shall be delivered consistent with the patient/family care plan.

(9) All social work services shall be documented in the patient/family record.

(10) Social work services shall be provided in accordance with recognized standards of social work practice.

(F) Direct Service Volunteer Services.

(1) The hospice shall provide direct service volunteer services.

(2) The hospice shall designate a coordinator of volunteer services who shall develop and implement a direct service volunteer program, coordinate the orientation, education, support and supervision of direct service volunteers, define the roles and responsibilities of direct service volunteers, and coordinate the utilization of direct service volunteers with other hospice staff.

(3) The coordinator of volunteer services shall document successful completion of a training and orientation program for all direct service volunteers.

(4) The orientation and training program for direct service volunteers shall address at least the following:

(a) the hospice program's goals and services;

(b) confidentiality and protection of patients/families rights;

(c) procedures for responding to such situations as medical emergencies or deaths;

(d) the physiological and psychological aspects of terminal disease;

(e) family dynamics, coping mechanisms, and psychosocial and spiritual issues surrounding terminal disease, death and bereavement;

(f) general communication skills.

(5) A direct service volunteer shall be informed of a patient's condition and treatment to the extent necessary to carry out his functions.

(6) Services provided by direct service volunteers shall be in accordance with the written plan of care and shall be documented in the clinical record.

(7) Direct service volunteers shall have the necessary qualifications and skills to provide the prescribed service.

(8) Any volunteer functioning in a professional capacity shall meet the standards of the appropriate profession.

(9) The hospice shall have available direct service volunteers sufficient to meet the needs of patients/families.

(G) Counseling Services.

(1) The hospice shall provide counseling services to assist patients and families as needed and in accordance with the plan of care.

(2) Counseling services shall be provided by professional staff or by volunteer staff under the professional supervision of a qualified counselor.

(3) Bereavement Counseling.

(a) The hospice shall provide bereavement services to the family following the patient's death.

(b) Bereavement services shall provide support to enable an individual/family to adjust to experiences associated with death.

(c) Bereavement services shall be available to the family for up to one year following the death of the patient.

(d) Bereavement services shall be delivered consistent with the bereavement plan of care and with criteria for termination of such services and/or referral of the family to other agencies or providers.

(e) Bereavement services shall be coordinated with other community resources judged by the interdisciplinary team to be useful to the family.

(f) Bereavement services shall be under the direction and supervision of a person qualified by training and experience for the development, implementation and assessment of a plan of care to meet the needs of the bereaved.

(g) All bereavement services provided shall be documented in the patient/family record.

(4) Spiritual Counseling.

(a) When spiritual counseling is provided to a patient/family by a hospice it shall be provided by a qualified interdisciplinary team member and/or through an arrangement with clergy and/or other spiritual counselors in the community.

(b) Hospice spiritual services shall be provided as desired by the patient/family and shall include but need not be limited to the following:

1. spiritual counseling in keeping with the patients/family beliefs;

2. communication with and support of appropriate clergy or other spiritual counselors in the community;

3. consultation and education to patients/families and interdisciplinary team members.

(c) When hospice spiritual services are provided through an arrangement with clergy and/or other spiritual counselors in the community there shall be documentation of ongoing communication between the clergy and/or other spiritual counselors and the interdisciplinary team members.

(d) The hospice shall make reasonable efforts to arrange for visits of clergy and or/other spiritual counselors in the community to patients who request such visits and shall advise patient families of this opportunity.

(e) Spiritual services shall be provided consistent with the plan of care and with criteria for termination of such services and/or referral to other agencies or providers.

(f) Spiritual services provided shall be documented in the patient/family record.

(5) Psychosocial/Supportive Counseling.

(a) When psychosocial/supportive counseling is provided by the hospice, it shall be provided by qualified counselors who are licensed, if applicable.

(b) A qualified counselor is an individual with an advanced degree in social work, psychology, mental health counseling, psychiatry or psychiatric nursing or the documented equivalent in education, training and/or experience and who has clinical experience appropriate to the counseling and casework needs of hospice patients/families.

(H) Inpatient Care.

(1) The hospice shall provide or arrange for short-term inpatient care for the control of pain and management of acute and severe clinical problems that cannot be managed in a home setting.

(2) Inpatient care shall be provided in hospitals licensed pursuant to M.G.L. c. 111, § 51 or long term care facilities licensed pursuant to M.G.L. c. 111, § 71 with whom the hospice has entered into a written contract, or hospice inpatient facilities directly owned and operated by a hospice program licensed pursuant to M.G.L. c.111 §57D.

(3) Contracts for inpatient care shall, in addition to the provisions of 105 CMR 141.212, include, at a minimum, the following mutually agreed upon terms:

(a) that the inpatient provider has established policies consistent with those of the hospice program and that the inpatient care facility agrees to abide by the patient care plan and protocol established by the hospice program;

(b) that the hospital or long term care facility will provide the hospice with a copy of the discharge summary and, if requested, a copy of the entire medical record; and

(c) that the hospice program shall make available appropriate hospice care training of hospital or long term care facility personnel who provide care under the agreement including staff orientation.

(4) Unless, pursuant to 105 CMR 141.099(B) the Commissioner waives the applicability of a particular hospice of one or more of the requirements imposed herein, the hospice, with respect to the hospice inpatient facility directly owned and operated by the hospice program, shall:

(a) meet the requirements of the federal Medicare Conditions of Participation for hospices that provide inpatient care directly (42 CFR 418.100);

(b) meet at least the building and physical plant requirements as modified from the general standards of construction for long term care facilities 105 CMR 151.000 et seq. as outlined in the Appendix A and additional physical plant requirements set forth in the federal Medicare Conditions of Participation for hospices that provide inpatient care directly (42 CFR 418.100).

(i) The space that constitutes a hospice inpatient facility shall be contiguous space.

(ii) If a hospice inpatient facility is located in a building that also houses other entities, the hospice inpatient facility shall not be used as a thoroughfare.

(c) provide nursing services directly and meet the following additional nursing staffing requirements:

(i) A registered nurse shall be designated as director of nursing (or equivalent title). He/she shall be a qualified registered nurse who has administrative authority, responsibility and accountability for the functions, activities and training of nursing services staff.

(ii) A registered nurse shall be on duty in the hospice inpatient facility to supervise nursing care and nursing personnel 24 hours a day.

(iii) One registered nurse may serve as both director of nursing and day shift nursing supervisor if he/she can carry out adequately the responsibilities of both positions.

(iv) Additional licensed nursing and other staff shall be provided to meet each patient's total care needs 24 hours a day.

(d) develop written policies and procedures governing infection control.

(i) Such policies shall provide for the proper disposal of infectious waste as required by 105 CMR 480.000 Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste State Sanitary Code Chapter VIII;

(ii) If the hospice inpatient facility's isolation room does not provide the mechanical exhaust ventilation prescribed by these regulations, the facility's policies must outline procedures for the transfer to a more appropriate facility of patients found to have any infectious disease transmitted by airborne pathogens. The hospice inpatient facility's admission policies shall preclude the admission of patients with known infectious diseases transmitted by airborne pathogens if the facility's isolation room does not meet the mechanical exhaust requirements prescribed in these regulations.

(e) meet the following dietary services requirements:

(i) All hospice inpatient facilities shall provide adequate dietary services to meet the daily dietary needs of patients in accordance with written dietary policies and procedures.

(ii) All hospice inpatient facilities shall have sufficient numbers of adequately trained personnel to plan, prepare and serve the proper diets to patients.

(a)All food service personnel shall be in good health, shall practice hygienic food handling techniques and shall comply with *105 CMR 590.000: State Sanitary Code Article X – Minimum Sanitation Standards for Food Service Establishments*.

(iii) All hospice inpatient facilities that admit patients in need of a special or therapeutic diet

shall provide for such diets to be planned, prepared and served as prescribed by the patient's physician.

(a) All therapeutic diets shall be planned, prepared and served with consultation by a dietician.

(iv) All meals and snacks shall conform to the quality standards of *105 CMR 590.000, the State Sanitary Code.*

(a) All food shall be maintained at safe temperatures. Food that is stored in a freezer shall be wrapped, identified and labeled with the date received and shall be used within the safe storage time appropriate to the type of food and the storage temperature. If not used within an appropriate time limit, the food shall be discarded.

(b) Equipment shall be provided and procedures established to maintain food at a proper temperature during serving and transportation. Hot foods shall be hot and cold foods shall be cold when they reach the patients.

(v) All utensils, equipment, methods of cleaning and sanitizing, storage of equipment or food, the habits and procedures of food handlers, rubbish and waste disposal, toilet facilities and other aspects of maintaining healthful, sanitary and safe conditions relative to food storage, preparation and distribution of food shall be in compliance with local health codes and *105 CMR 590.000: State Sanitary Code Article X – Minimum Sanitation Standards for Food Service Establishments.*

(f) The Medical Director or his/her physician designee shall conduct regular onsite visits to the inpatient facility, including daily visits if necessary to assess patient conditions and reevaluate medical orders of unstable patients.

<u>141.205: Patient Rights and Responsibilities</u>

(A) Each hospice shall have written policies and procedures that protect the rights of all patients/families. Rights shall include but need not be limited to:

(1) the right to be informed of the hospice philosophy and concept, admission criteria, services to be provided, any third party coverage and personal charges, and any sliding fee scale associated with services provided

(2) the right to confidentiality of all records and communications

(3) the right to informed consent

(4) the right to participate in developing the patient care plan

(5) the right to refuse service or withdraw from the program at anytime.

(B) A copy of patient/family rights and a statement of patient/family financial responsibilities shall be provided to the patient/family and shall be signed by the patient and family upon admission. If the patient has no family the copy of patient/family rights shall be signed by the patient and the primary care giver, if the hospice's admission criteria require a primary care giver.

(C) If the hospice provides any services under contract agreements, each patient/family shall be provided upon request with written information that clearly defines the services provided under contract and identifies the contracted individual(s) or organization(s).

(D) Each patient/family seeking services shall receive a written explanation of the third party benefits available to the patient/family through the hospice, including any restrictions.

141.206: Policies and Procedures

(A) The hospice shall develop and implement written policies and procedures to coordinate an interdisciplinary program of hospice care services.

(B) These policies and procedures shall be reviewed and approved by the Governing Body at least annually.

(C) The policies and procedures shall include but need not be limited to:

(1) philosophy, objectives and goals of the hospice

(2) the services to be provided and record keeping requirements for clinical records

(3) criteria for the selection, admission, discharge and transfer of terminally ill patients/families

(4) affiliation or and referral arrangements with community and other health care facilities or agencies to assure continuity of patient/family care

(5) the hospice's professional management responsibilities for overseeing services provided under contractual arrangements

(6) patient/family consent and involvement in the development of a care plan

(7) patient/family education

(8) plans and arrangements for the patient's death whether at home or in an institution

(9) community education

(10) patient and family rights

(11) review of the quality and utilization of hospice services

(12) resuscitation practices

(13) infection control

141.207: Pharmaceutical Services and Medications

(A) All hospices shall maintain current written policies and procedures regarding the administration and recording of drugs and biologicals.

(B) Hospices shall comply with all Federal and State laws and regulations (including 105 CMR 700.000 et seq.) relating to the procurement, storage, dispensing, administration, recording and disposal of drugs.

(C) No drug or medication that has been removed from the market by the Food and Drug Administration shall be stocked or administered by a hospice.

(D) The hospice shall make arrangements for 24-hour availability of medications.

(1) If the hospice program admits pediatric patients, it shall provide age and size appropriate drug administration and dosing.

E) There shall be a current written order by a physician, nurse practitioner or physician assistant in the patient's clinical record for all medications or drugs administered by hospice staff to the patient. All drugs and medications the patient receives shall be recorded on a profile sheet which shall be kept as part of the patient's clinical record.

(1) Verbal or telephone orders shall be given only to a licensed nurse and shall be immediately recorded in writing in the patient's clinical record and signed by the same nurse. All verbal or telephone orders shall be countersigned by a physician, physician assistant or nurse practitioner within 21 days.

(2) If medications for a patient are ordered by a physician assistant or nurse practitioner, all initial orders for medication or significant changes in medications and all orders for Schedule II drugs must be reviewed by the supervising physician as specified in 105 CMR 700.000 et seq.

(3) If medications for a patient are ordered by a physician assistant or nurse practitioner, there shall be a general review of medications by the physician assistant or nurse practitioner and the supervising physician as specified in 105 CMR 700.000 et seq.

(4) Orders for medication and treatments shall be in effect for the specific number of days indicated by the physician, physician assistant or nurse practitioner.

(5) Hospice staff administering drugs shall be appropriately licensed to carry out this function.

(F) The primary care persons and each drug and biological they are instructed to administer must be specified in the patient's plan of care.

(G) All medications administered by the hospice staff shall be accurately recorded in the patient's clinical record with the signature of the person administering the medication.

(H) Hospice staff, patients/families and primary caregivers shall be made aware of the signs and symptoms, of the side effects of drug therapy.

(I) Hospice staff shall have access to references for drug interaction and drug dosing.

141.208: Admissions

(A) The hospice shall establish written admission criteria and policies which shall include an assessment of the patient's/family's desire and need for hospice service, and any eligibility limitations of a patient who does not have a designated primary care giver.

(B) Admission to a hospice shall be limited to patients

(1) who are terminally ill with a limited life expectancy,

(2) who are no longer receiving treatment for cure,

(3) who along with the physician and family agree that palliative care is appropriate, and

(4) who have elected to receive hospice care.

(C) Each hospice shall define in writing the term "limited life expectancy" in its admission policies.

(D) The patient, or a representative of the patient's family unit if the patient is not able, must sign an informed consent agreement.

141.209: Clinical Records

(A) The hospice shall maintain in a centralized location at the hospice administrative office an accurate clinical record for every individual receiving care and services.

(1) When a hospice patient is admitted to a hospice inpatient facility, a copy of the patient's plan of care and sufficient relevant supporting documentation to ensure coordination of care shall be transmitted to the inpatient facility. When the patient is discharged from the hospice inpatient facility, a medical record and discharge summary shall be transmitted to the hospice administrative office to be included in the patient's clinical record.

(B) The record shall be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval. The refusal of services shall also be documented.

(C) Record entries shall be made and signed by the person providing the service for all services provided.

(D) The record shall include documentation of all services whether furnished directly or under arrangements made by the hospice.

(E) Each individual's record shall include:

(1) the initial and subsequent assessments;

(2) the plan of care;

(3) identification data;

(4) consent forms;

(5) pertinent medical history;

(6) complete documentation of all services and events (including evaluations, treatments, progress notes etc.);

(7) physicians' orders;

(8) medication records;

(9) discharge/transfer records;

(10) all pertinent diagnoses;

(11) the patient's prognosis;

(12) designation of the attending physician;

(13) a bereavement assessment and plan for intervention, if any;

(14) instructions to the family concerning care if patient is discharged.

(F) The hospice shall safeguard the clinical records against loss, destruction and unauthorized use.

(G) All records shall be maintained for a period of seven years after death or discharge.

(H) Each hospice shall establish policies and procedures to govern the use, removal and, permanent disposition of records and determine the conditions of release of information in accordance with maintaining confidentiality.

141.210: Quality Assurance

(A) The hospice shall develop and implement, through an interdisciplinary committee, an ongoing quality assurance program. One member of the committee shall be designated to be responsible for coordinating quality assurance.

(B) The quality assurance program shall include an evaluation of all services, including any services provided to patients under contractual arrangements. The hospice shall offer contracted hospice providers the opportunity to participate in the quality assurance program.

(C) Each hospice shall establish a written quality assurance plan for review of services delivered. The plan shall include:

(1) A procedure for evaluating care provided on individual cases. At least quarterly, members of professional disciplines representing at least the scope of the hospice program shall review a 10% sample of both active and inactive clinical records of care delivered to hospice patients and families. A written summary shall be prepared for each individual review commenting on the amount and kind of care delivered and including statements addressing any unmet needs.

(2) A process for program evaluation and the identification of problems. At least quarterly, all summaries of individual reviews shall be reviewed by the person responsible for coordinating quality assurance. A written report will be prepared addressing any identified problems with care, treatment, services, availability of services, and methods of care delivery.

(3) A system to report to the governing body the findings and recommendations for improving the quality of care delivered. The quality assurance reports shall be submitted to the hospice Administrator and Governing Body. There shall be evidence in the Governing Body's meeting minutes that the reports have been reviewed by the Governing Body at least annually.

141.211: Data Collection

(A) Each hospice shall establish and maintain records and data in such a manner as to make uniform a system of periodic reporting. The manner in which the requirements of 105 CMR 141.000 shall be met shall be prescribed from time to time in directives developed by the Department.

(B) Each hospice shall report to the Department statistical data pertaining to its operation and services including demographic and service utilization data. Such reports and data shall be made at such intervals and in such form and manner as prescribed by the Department.

141.212: Contractual Services

(A) A hospice may contract with other health care providers for the provision of all required services.

(B) All contracted services shall meet the applicable provisions of 105 CMR 141.000 et seq.

(C) The hospice program shall assure continuity of patient/family care in home, outpatient and inpatient settings.

(D) The hospice program shall retain professional management responsibility for contracted services and ensure they are furnished in a safe and effective manner by qualified personnel in accordance with the patient's plan of care.

(E) When services are not provided directly by a hospice a written agreement shall define the scope of contracted services and the manner of maintaining continuity of care between contracted services and those services provided directly by the hospice. The agreement shall at a minimum specify the following:

(1) the services to be provided;

(2) the duties and responsibilities of each of the contracting parties for the coordination and supervision of care, including delineation of the role(s) of the hospice and contractor in the admission process, patient/family assessment and the interdisciplinary group care conferences;

(3) the stipulation that the hospice is responsible for all hospice services whether or not the services are furnished under contract and may only be provided with the express authorization of the hospice;

(4) the financial and reimbursement arrangements, including any arrangements for donated services;

(5) the manner in which contract services shall be coordinated, supervised, and evaluated by the hospice program;

(6) requirements for documenting that services are furnished in accordance with the agreement; and

(7) qualifications of the personnel providing the services.

(F) Contracts shall be dated and signed by an authorized agent of the hospice and the contracting agency.

(G) All contracts shall be reviewed and/or revised by the hospice on an annual basis.

(H) The quality of the contracted services shall be regularly evaluated by the hospice as specified in 105 CMR 141.210.

141.299: Appendix A: General Standards of Construction: Hospice Inpatient Facility Directly Owned and Operated by a Hospice Program

Definitions:

Identifiable Unit shall mean a section of a hospice inpatient facility such as a wing, floor or ward and shall include adjacent rooms where acceptable to the Department. For all new construction, additions, conversions or alterations, an identifiable unit shall mean not more than 20 beds. A nursing unit shall not encompass beds on more than one floor.

Site Improvements:

Parking

Designated parking shall be provided in accordance with the provisions of local zoning and building ordinances, but in no case shall the ratio of offstreet parking be less than one parking space for each four beds.

Exception to this requirement may be granted only with the approval of the Department.

Provisions for Handicapped

(A) Gradients of Walks. Public walks shall be not less than 4 feet wide and shall have a gradient of not greater than 8%.

(B) Walks - Continuous Surface. Walks shall be of a continuing common surface, not interrupted by steps or abrupt changes in level. Wherever walks cross other walks, driveways or parking lots, they shall blend to a common level.

(C) Handicapped Parking.

(1) At least one parking space shall be provided and identified for use by the physically handicapped. These spaces shall be in close proximity to the building entrance.

(2) Such parking spaces, if diagonal or headon, shall be not less than 12 feet wide to allow proper access in or out of vehicles.

(3) Walks and ramps from parking areas, garages, etc. shall conform to (A) and (B) above.

(4) Access from parking areas through a primary building entrance shall be a continuous level or ramped surface without steps or abrupt changes in level.

Nursing Care Units:

Required Supporting Elements -- Nursing Care Units A unit shall have, centrally located within its area, a nurses' station, a medicine room or closet, a soiled utility room, a clean utility room, a linen storage closet, a drinking fountain or water cooler, a janitor's closet and a room for the storage of supplies and equipment.

Patient Bedrooms -- Nursing Care Units

(A) The floor area of patient bedrooms, excluding closet, vestibule and toilet room areas shall not be less than 125 square feet. Additional space may be needed if family/friends stay with the patient.

(B) All patient bedrooms shall be private rooms.

(C) Rooms shall be shaped and sized so that each bed can be placed at least three feet from any lateral wall. An unobstructed passageway of at least four feet shall be maintained at the foot of each bed. Variations in bed placement and dimensions shall be permitted only with the approval of the Department.

(D) Patient bedrooms shall have a floor level at least six inches above the grade level adjacent to the building.

(E) All patient bedrooms shall be along exterior walls with window access to the exterior.

(F) All patient bedrooms shall open directly to a main corridor and shall be permanently and clearly identified by a distinctive name or number on or beside each entrance door.

(G) Each patient bedroom shall contain closet space for the storage of personal belongings. In addition, either a built-in or free-standing multiple-drawer bureau shall be provided.

(H) Each patient bedroom shall be sized and dimensioned to accommodate hospital-type beds of not less than 76 inches long and 36 inches wide, a hospital-type cabinet and an easy chair or comfortable straight-back arm chair.

(a) For facilities that admit pediatric patients, service equipment (e.g., beds, cribs, wheelchairs and toys) shall be age and size appropriate.

(I) Each patient bedroom shall have direct access to an adjacent toilet room equipped with a toilet and handwashing sink. The toilet room shall be handicapped accessible.

(a) For facilities that admit pediatric patients, when a pediatric patient is admitted there shall be a designated bathroom for pediatric use only.

(J) Bedrooms used by pediatric patients shall be adjacent to the nurses' station. Observation of the rooms must be possible from the nurses' station.

Nurses' Station

(A) A nurses' station shall be conveniently located within each nursing unit.

(B) Each nurses' station shall be provided with a desk or counter and chart racks.

Medicine Room/Closet-- Nursing Care Units

(A) A separate, locked medicine room/closet shall be provided in close proximity to each nurses' station.

(B) Each medicine room/closet shall contain a top and base cabinet. The base cabinet shall be equipped with a counter top and a sink with hot and cold running water.

(C) A separate locked compartment shall be provided for the storage of narcotics and other dangerous drugs.

(D) Each medicine room/closet shall contain a refrigerator for medication that requires refrigeration.

(E) Poisons and medications for external use only shall be kept in a locked cabinet or compartment separate and apart from internal medicines.

Day Room/Dining Room/Nursing Care Units

(A) One day room solarium, sitting room or equivalent area shall be provided in each unit for activities and dining.

(B) At least one dining area shall be provided for patients who can and wish to eat at a table. Combined use of one room for both activities and dining functions shall be permitted provided such room is adequately equipped and furnished to accommodate both functions.

Isolation Room

(A) One single bedroom shall be provided for occupancy by a patient requiring isolation. This room shall not have direct access with any other patient room. The room shall be included in the quota and may be generally used until such time as it is needed for isolation.

(B) The isolation room shall be provided with a separate toilet, sink and shower.

(C) If the hospice inpatient facility admits or treats patients with infectious diseases transmitted by airborne pathogens, the isolation room must have mechanical exhaust ventilation that provides at least 10 air changes per hour.

Patient Bathing Facilities

(A) Bathing facilities shall be provided in a ratio of not less than one per 15 patients. If a bathtub is provided, it shall be a free-standing type tub accessible from two sides and one end with a minimum three foot clearance. The tub shall be equipped with an acceptable type bath lift.

Shower floors shall be flush and shall be without curbs. The floor shall be sloped to the center of the shower stall. Mixing valves and controls shall be mounted outside the shower stall. Shower enclosure shall be not less than 30 inches by 60 inches. All common bathing facilities shall be separated by solid wall partitions or dividers.

(B) Grab Bars Required for Tubs, Showers, and Toilets. All tubs, showers and toilet enclosures shall be equipped with grab bars. Grab bars, accessories and anchorage shall have sufficient strength to sustain a dead weight of 250 pounds for five minutes.

(C) Hot Water Supply: Maximum Temperature. Hot water supplied to fixtures accessible to patients shall be controlled to provide a maximum temperature of 110F.

Storage Areas -- Nursing Care Units

(A) Linen Closet. A linen storage closet shall be provided in each unit for the storage of daily linen needs.

(B) Janitor Closets.

(1) One janitor's closet shall be provided for each unit. In no event shall there be less than one janitor's closet per floor.

(2) Each janitor's closet shall contain a service sink equipped with hot and cold running water.

(3) Each janitor's closet shall have adequate shelving for the storage of cleaning supplies and housekeeping equipment.

(C) General Storage.

(1) In each unit, a storage closet shall be provided for the storage of supplies and equipment. The clean area shall be large enough to permit easy storage of wheel chairs, lockers, patient's lifts and other types of mechanical equipment.

(2) Where oxygen storage is provided it shall be in accordance with the National Fire Protection Association Life Safety Code.

Utility Rooms -- Nursing Care Units

(A) Soiled Utility Room. The soiled utility room shall contain a service sink with gooseneck faucet and hot and cold running water; a clinical service sink; a work counter and handwash facilities; and space for waste containers and soiled linen hampers.

(B) Clean Utility Room. The clean utility room shall contain wall hung and base cabinets. The base cabinet shall be equipped with a counter top and sink with hot and cold running water and a gooseneck spout.

Common Service Elements:

Storage Areas

(A) General Storage. A general storage room or rooms shall be provided in each facility.

(B) Linen Storage.

(1) A central linen area shall be provided within each facility.

(2) A central soiled linen room shall be provided within each facility with handwashing facilities.

(3) Laundry chutes, when provided, shall be locked and terminate in the soiled linen room. Sufficient space shall be provided to accommodate a laundry hamper.

(C) Central Food Storage. A room or other separate storage area(s) shall be provided for the storage of non-perishable foods.

Office Space

(A) Administrative Offices.

(1) Appropriate space and equipment shall be provided for administrative activities and for the storage of medical records.

(2) At least one office shall be provided for the use of the Administrator and the Director of Nurses.

(B) Consultant Offices. Consideration shall be given to provide separate rooms for the use of full-time consultants, such as a medical director, dietitian, social worker and others.

Staff and Public Toilets and Washrooms

(A)Toilets and handwashing facilities shall be provided for visitors and staff separate from those facilities used by patients.

(B) One handicapped accessible, gender-neutral toilet room equipped with toilet and handwashing sink shall be provided for staff and visitors on each unit.

(C) Visitors and staff toilets shall have toilet paper holders and toilet paper, paper towel dispensers and paper towels, soap dispensers with soap and mirrors.

Nourishment Kitchen

(A) A nourishment kitchen room or alcove shall be conveniently located on each floor and shall be available for patient use.

(B) The nourishment kitchen shall contain a refrigerator, surface cooking unit or microwave oven, a toaster, a sink with hot and cold running water, and storage cabinets.

Meal Service Facilities

(A)Meal service facilities shall meet the requirements set forth in the Medicare Conditions of Participation for hospices that provide inpatient care directly (42 CFR 418.100).

(B) If pre-prepared meals or meals prepared off the premises are used, dietary areas and equipment shall be designed to accommodate the requirements for safe and sanitary storage, processing and handling.

(C) If a hospice inpatient facility has an onsite kitchen, the kitchen shall have a food preparation area, food storage area, dishwashing area, janitor's closet, delivery and receiving areas and administrative space.

(1) The kitchen shall be equipped at a minimum with:

(a) a handwashing sink with hot and cold running water and towel dispenser with disposable towels and a soap dispenser with soap;

(b) a double-compartment sink with hot and cold running water and an attached drainboard and backsplash for food preparation;

(c) a service sink with hot and cold running water and an attached drain board on each side, with backsplash, for the washing of pots and pans;

(d) mechanical refrigeration for storing perishable food, with a maximum temperature of 41°F. Freezers or frozen food compartments shall be maintained at or below 0°F. Thermometers shall be attached to the inside of all refrigerators, freezers and frozen food compartments;

(e) conventional cooking and baking equipment; and

(f) an automatic dishwasher capable of handling the needs of the facility. In a dishwashing machine the temperature of the wash water shall be between 140°F and 160°F, with a final rinse at a temperature of 170°F or higher, or follow the manufacturer's recommendations.

(2) Enclosed cabinets shall be provided for the storage of dishes, silverware and other eating

utensils.

(3) The kitchen shall be located to avoid through traffic.

(4) A janitor's closet shall be provided for kitchen use.

Laundry

When laundry service is to be performed on the premises, sufficient space and equipment, including at a minimum a utility sink, washer, dryer, and shelving for laundry supplies, for such service shall be provided.

Visitors' Room

A separate quiet room shall be provided for visitors.

Staff Lounge

A designated space shall be provided as a staff lounge area.

Sleep Area

A comfortable and accessible sleep area shall be provided for family members.

Architectural Details:

Corridors

(A) For new construction or conversion of a building not previously licensed as an inpatient health care facility, corridors in areas used primarily by patients shall not be less than eight feet wide and all other corridors shall be not less than five feet wide. Conversion of a building previously licensed as an inpatient health care facility shall maintain existing corridors widths, however, in no instance shall corridor widths be less than four feet.

(B) Handrails shall be provided on both sides of corridors. Handrails shall be firmly anchored and shall not project more than 3½ inches into the required minimum width of the corridor and shall be no less than 30 inches above the finished floor. They shall have curved returns.

(C) A facility shall not permit the installation of any fixed appurtenance that may become an obstacle to traffic or reduce the required minimum width of corridor, ramp or stair.

Ramps

(A) Interior ramps in areas used by patients shall meet the corridor width requirements. Outside ramps shall be not less than four feet in width.

(B) Ramp surfaces shall be constructed and maintained in such a manner as to prevent slipping thereon.

(C) Street or ground floors having exits to the exterior above grade shall have at least one ramp leading to grade to accommodate wheelchair and litter patients.

(D) Handrails shall be provided on both sides of all ramps. Specification as to height, anchorage and curved returns as required for corridor handrails.

(E) Ramps shall have a gradient of not greater than 8%.

Stairs and Stairways

(A) Surfaces of treads and landings shall be constructed and maintained so as to prevent slipping.

(B) Handrails shall be provided on both sides of all indoor and outdoor stairways. Specifications as to height, width and anchorage as required for corridor handrails. They shall have curved returns.

(C) Steps in stairways shall not have abrupt (square) nosing, and risers shall be tapered back approximately 1 inches at bottom of each riser. Risers where possible should not exceed seven inches. Stair widths shall be able to accommodate a litter or stretcher for emergency patient evacuation.

Doors and Doorways

(A) All doors used by patients shall be swing-type and shall comply with applicable Life Safety Code requirements for new health care occupancies except toilet room doors shall be at least 36 inches wide and, if in-swinging, have pivots and manually operated emergency release.

(B) No locks or hooks shall be installed on doors used by patients.

(C) If the facility admits pediatric patients, linen and janitor closets and storage and utility rooms shall be locked.

(D) All outside doors and doorways shall be made draft-free by the installation of weather stripping or caulking material.

Windows

(A) In order to furnish natural fresh air, at least one window in each patient bedroom shall be operable at all times without the use of tools.

(B) Openable windows shall be provided with screens constructed from not less than 16 mesh wire screening.

(C) All outside windows shall be made draft-free by the installation of either weather stripping or caulking material.

(D) All windows shall be designed to prevent falls when open.

Mechanical Details:

Heating and Cooling Systems

(A) Every facility shall be equipped with a heating system which is sufficient to maintain a minimum temperature of 75°F throughout the facility at all times at winter design temperatures.

(B) Heating fixtures and all exposed pipes shall be shielded for the safety of patients.

(C) Each heating fixture shall be equipped with hand controls unless an individual automatic room control is provided, except where baseboard radiation is utilized.

(D) Air conditioning shall be provided in each patient room.

Ventilation Systems

(A) Mechanical exhaust ventilation shall be provided, regardless of natural ventilation, and must be capable of assuring the minimum number of air changes per hour for the following areas:

(1) For facilities that admit patients with infectious diseases transmitted by airborne pathogens, the isolation room shall have at least 10 air changes per hour.

(2) Kitchens, dishwashing areas and diet/nourishment kitchens shall have at least ten air changes per hour.

(3) Bathrooms, toilets and showers shall have at least ten air changes per hour.

(4) Rooms for soiled linen shall have at least ten air changes per hour.

(5) Utility rooms, janitor's closets, laundry rooms and nurses' stations shall save at least ten air changes per hour.

(6) Oxygen storage rooms shall have at least 10 air changes per hour.

(B) Storage rooms other than oxygen storage rooms, including food storage rooms, boiler rooms and rooms in which mechanical equipment is stored, shall have separate and independent venting systems providing not less than two air changes per hour.

(C) Ducts for ventilating bathrooms, the isolation room, toilets, rooms for soiled linen, laundry rooms and garbage storage rooms shall not be interconnected with other duct systems, but shall lead to the outside independently.

(D) All ducts penetrating floors or fire rated walls shall be fire dampered at the point of penetration.

(E) Corridors and exit halls shall not be used as plenums for the supply or return air to heating or air conditioning systems.

(F) Exhaust air intakes or hoods shall be located at cooking, dishwashing and high steam or fume-producing areas.

Water Supply

(A) The volume and pressure of the water supply shall be sufficient to supply water to all fixtures with a minimum pressure of 15 pounds per square inch at the farthest point of usage during maximum demand periods.

(B) Domestic hot water heating equipment shall have adequate capacity to supply the following:

	Patient Area	Food Preparation Center	Laundry
Gal/hr/bed	6 1/2	4	4 1/2
Temp. [degrees] F	110	180	180

(C) Water shall be obtained from an approved municipal water system or, in areas where wells are the source of supply, they shall be designed and constructed with the approval of the Department.

Sewerage

All sewage shall be discharged into a municipal sewerage system where such is available; otherwise, the sewage shall be collected, treated and disposed of by means of an independent sewerage system designed and constructed with the approval of the Department.

Elevators

(A) Each facility with patients housed on other than the street floor shall provide at least one elevator of hospital type.

(B) Each facility of one-story construction, in which ancillary patient services are located in the basement or below grade, shall provide a hospital type elevator to accommodate patient transportation to those areas.

(C) The interior cab dimension shall be not less than 5'0" x 7'6" and the door opening not less than 44 inches.

Electrical:

Lighting

(A) Electric lighting shall be provided throughout the facility in accordance with the recommended levels of the illuminating Engineering Society. All electrical installations shall be in accordance with 527 CMR 12.00: Massachusetts Electrical Code.

(B) Adequate lighting fixtures shall be installed in each patient room to provide uniform distribution of light.

(C) Outside walks, parking lots and entrances shall be adequately lighted.

Night Lights

(A) Night lights shall be provided in corridors, stairways, bathrooms, toilets, nurses' stations, and patient bedrooms.

(B) Night lights in patient rooms shall be appropriately located and not less than 12 inches above the finished floor. Fixtures shall be recessed into the wall and shall have slotted covers to produce a subdued light.

(C) Night lights in patients' toilets shall be not less than 15 watts. Fixtures shall be mounted not less than 12 inches from the finished floor.

(D) All night lights shall be controlled either by a switch at the entrance to the patient bedroom or from the nurses' station.

Reading Lamps

A reading lamp shall be provided for each patient. If wall-mounted bed lamps are provided they shall be not less than 64 inches from the finished floor and be mounted directly over each bed.

Emergency Electrical Systems

(A) An emergency source of electricity shall be connected to circuits designated below for lighting and power to provide electricity during an interruption of the normal electric supply that could affect the nursing care, treatment or safety of the occupants.

(B) The emergency source of electricity shall consist of a generating set, including the prime mover and generator. It shall be located on the premises and shall be reserved exclusively for supplying the emergency electrical system. The set shall be of sufficient kilowatt capacity to supply all lighting and power demands of the emergency system. The power factor rating of the generator shall be not less than 80%.

(C) Emergency electrical connections shall be provided to circuits for lighting of stairways, corridors, exit ways and exterior approaches thereto, exit and direction signs, nurses' stations, medicine preparation areas, kitchen, dining and recreation areas, generator set location and boiler room.

(D) Emergency electrical connections shall be provided for protection of vital equipment and materials and for operation of equipment essential to health and safety of the occupants, including but not limited to nurse's call, alarm system, fire pump (if installed), sewerage or sump lift pumps (if installed), one duplex receptacle per bed, corridor duplex receptacles, one elevator, equipment for maintaining telephone service, paging or speaker systems, refrigerators, freezers, and equipment such as burners and pumps necessary for operation of one or more boilers and their controls required for heating.

(E) Where electricity is the only source of power normally used for space heating, the emergency service shall provide for heating of patient rooms unless the hospice inpatient facility is supplied by at least two utility service feeders, each supplied by separate generating sources.

(F) An automatic transfer switch shall be installed to transfer to emergency power within ten seconds.

Electrical Outlets

(A) Patient rooms shall have not less than one duplex receptacle per bed and in addition, one receptacle on a wall other than the bed headwall. Duplex receptacles shall be installed so as to meet the needs in any given area.

(B) Outlets for portable tray carts shall be provided.

Call Systems

(A) A nurse's calling station shall be installed at each patient bedside, in each patient's toilet, bath and shower room, and in other patient care areas.

(B) The nurse's call in the toilet, bath and shower rooms shall be an emergency call.

(C) For a hospice inpatient facility that occupies a building with another health care facility, the hospice inpatient facility’s call system shall not be connected to the other health care facility’s call system.

Telephone Systems

(A) At least one telephone shall be provided on each floor. These telephones shall be free of locks and available 24 hours daily for use in any emergency.

(B) In addition, there shall be provisions for bedside telephones for each patient who requests a telephone.

Medical Equipment

Medical equipment that is age and size appropriate shall be available on site when the hospice inpatient facility admits a pediatric patient.